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UNCLAS ANKARA 004058

SIPDIS

DEPT FOR EB/TPP/MTA/IPE - JURBAN AND EUR/SE
DEPT PASS USTR FOR LERRION/JCHOE-GROVES
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USDOC FOR ITA/MAC/DDEFALCO

SENSITIVE

E.O. 12958: N/A

TAGS: [ETRD](#) [KIPR](#) [EAGR](#) [TU](#)

SUBJECT: Zyprexa Update- MOH Issues Sales and Marketing
Permits for the Generic Producer

SENSITIVE BUT UNCLASSIFIED. PLEASE HANDLE ACCORDINGLY.

1.(SBU) SUMMARY: ELI LILLY TURKEY CONFIRMED THAT THE MINISTRY OF HEALTH (MOH) ISSUED SALES AND MARKETING PERMITS FOR THE GENERIC COPY OF ZYPREXA IN LATE JUNE. FOLLOWING THIS DEVELOPMENT, THE ISTANBUL SPECIALIZED IPR COURT ISSUED A PRELIMINARY INJUNCTION, PREVENTING THE GENERIC PRODUCER FROM SELLING OR DISTRIBUTING ITS PRODUCTS. ELI LILLY IS PLEASED WITH THE COURT RULING, PARTICULARLY WITH THE COURT'S RECOGNIZING THE EXISTENCE OF A POTENTIAL PATENT INFRINGEMENT. TECHNICAL EXPERTS FROM LILLY AND ABDI IBRAHIM (THE GENERIC PRODUCER) WILL MEET TO DISCUSS POSSIBLE PATENT INFRINGEMENT IN THIS CASE AND SUBMIT A REPORT TO THE COURT. THE GENERIC PRODUCER'S PERMIT WILL BE CANCELLED IF THE COURT DECIDES THERE IS A PATENT INFRINGEMENT. ELI LILLY REPRESENTATIVES DISCUSSED THE COURT RULING WITH THE MOH, AND OFFERED THEIR ASSISTANCE IN ESTABLISHING AN EFFICIENT SYSTEM TO PREVENT THESE PROBLEMS IN THE FUTURE. ELI LILLY TURKEY WILL HAVE A MEETING NEXT WEEK TO DISCUSS THEIR FOLLOW-ON STRATEGY. END SUMMARY.

12. (SBU) ECON SPECIALIST CONTACTED RAZIYE GEDIKLI, ELI LILLY CORPORATE AFFAIRS DIRECTOR, ON JULY 12 TO RECEIVE AN UPDATE ON THE ZYPREXA CASE. GEDIKLI SAID THE MOH ISSUED SALES AND MARKETING PERMITS FOR ZYPREXA'S GENERIC COPY IN LATE JUNE. FOLLOWING THIS NEWS, THE ISTANBUL SPECIALIZED IPR COURT ISSUED A PRELIMINARY INJUNCTION IN AN ONGOING ZYPREXA COURT CASE, WHICH PREVENTED THE GENERIC PRODUCER (ABDI IBRAHIM) FROM SELLING OR DISTRIBUTING ITS PRODUCTS UNTIL THE FINAL VERDICT. LILLY IS VERY PLEASED WITH THE RULING, I.E. THAT THE COURT AGREES THERE IS A POTENTIAL PATENT INFRINGEMENT IN THIS CASE. GEDIKLI SAID THE POSITIVE COURT RULING WAS DUE MAINLY TO THE COURT'S BEING A SPECIALIZED IPR COURT AND THE MOH'S DISCLOSING THE DOCUMENTS REQUESTED BY THE COURT. THE NEXT STEP IS TO HAVE THE EXPERTS FROM LILLY AND ABDI IBRAHIM GET TOGETHER TO EXAMINE EXISTENCE OF A PATENT INFRINGEMENT IN THIS CASE, FOLLOWED BY A COURT HEARING. THE PERMITS WILL BE CANCELLED IF THE COURT DECIDES THERE IS A PATENT INFRINGEMENT- THE COMPANY WILL START SELLING AND DISTRIBUTING ITS GENERIC PRODUCT IF THE COURT DECIDES OTHERWISE.

13. (SBU) GEDIKLI SAID SHE VISITED HEALTH DEPUTY UNDERSECRETARY ORHAN GUMRUKCUOGLU AFTER RECEIVING THE COURT RULING. GUMRUKCUOGLU REPORTEDLY SAID THAT THE MINISTRY DID NOT VIOLATE ANY LAWS BY ISSUING THE PERMITS, BUT CLAIMED HE WAS PLEASED THAT LILLY WAS ABLE TO GET A PRELIMINARY INJUNCTION FROM THE COURT. GEDIKLI SAID GUMRUKCUOGLU WAS QUITE SURPRISED WITH THE COURT DECISION, SINCE THIS WAS THE FIRST RULING IN FAVOR OF LILLY FOLLOWING SEVERAL NEGATIVE RULINGS IN THE PAST. SHE COMMENTED THAT THE GAPS IN THE LEGISLATION ENABLED THE MOH TO ISSUE THE PERMITS. GEDIKLI SAID LILLY GAVE THE MESSAGE TO THE MOH THAT THERE WAS A CONFLICT BETWEEN THE MOH'S IMPLEMENTATION AND THE COURT DECISION, WHICH REVEALED THE EXISTENCE OF A PROBLEM WITH THE "SYSTEM." LILLY SUGGESTED TO THE MOH THAT THEY WORK TOGETHER TO RESOLVE THE PROBLEM AND ESTABLISH A NEW SYSTEM.

14. (SBU) GEDIKLI SAID ANOTHER POSITIVE DEVELOPMENT THEY HAD RECENTLY WAS RECEIVING A RESPONSE FROM THE MOH REGARDING THEIR REQUEST ON THE NAMES OF THE OTHER COMPANIES WHICH APPLIED FOR GENERIC COPIES OF ZYPREXA'S MOLECULE OLENZAPIN. THE MOH'S RESPONSE REVEALED THAT THERE WERE 12 COMPANIES WHICH APPLIED FOR THE SAME MOLECULE, WHICH WAS HIGHER THAN LILLY'S ESTIMATE OF 5 COMPANIES.

15. (SBU) GEDIKLI SAID LILLY WAS "NEUTRAL" ABOUT THE NEWS ON MOH'S ISSUING SALES AND MARKETING PERMITS FOR ABDI IBRAHIM FOR THE MOMENT, AND THEY HAD NOT COME UP WITH A STRATEGY YET. GEDIKLI TOLD US ELI LILLY TURKEY REPRESENTATIVES WERE PLANNING TO MEET NEXT WEEK TO DISCUSS NEXT STEPS.